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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,563	07/24/2001	Thomas P. Osypka	695716.0016 (OSCO-114)	6118

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EDWARDS AND ANGELL  
PO BOX 9169  
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EXAMINER

MAYNARD, JENNIFER J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/13/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/911,563

Applicant(s)

OSYPKA ET AL.

Examiner

Jennifer J Maynard

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12, 16 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16 and 25-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether Applicant intends to claim an elongated cylindrical plug body has a central core which increases the flexibility of the plug body relative to the flexibility that the plug body would exhibit without having a central core, or a flexible central core which merely makes the plug body as a whole more flexible than prior art plug bodies. Clarification and correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 4, 6, 8-12, 16, 25, 26 and 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Hubert (US 3,572,333 A).

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Hubert discloses an apparatus for facilitating vascular access comprising a vascular access port (15) defining an elongated tubular body (16) of predetermined length with a central lumen bounded by a continuous, uninterrupted outer wall, the tubular body having opposed proximal and distal end portions and an inner diameter, the distal end portion adapted and configured for introduction into a blood vessel; and an elongated cylindrical plug (10, 12) dimensioned and configured for insertion into the central lumen of the vascular access port and ready removal therefrom to permit access to the blood vessel, the plug body having a length that is substantially equal to the vascular access port and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent blood flow between the outer diameter of the plug and the inner diameter of the lumen of the access port when the plug is engaged therein; and a locking mechanism (27, 29) associated with the proximal end of the elongated cylindrical plug body adjacent a handle portion (20) thereof for releasably coupling the plug body to the vascular access port, see Column 1, line 69 through Column 2, line 5, Column 3, lines 13-24 and Figures 1 and 2.

With regard to Claims 16 and 33, the Examiner has taken the position that given Hubert's disclosed elongated cylindrical plug is made in the form of a solid, flexible plastic stem, it would inherently have a central core which increases the flexibility of the plug as the overall material is flexible in nature and would thus be comparatively more flexible than if the plug were made of a more rigid material. This interpretation is possible because Applicant's claim language has failed to structurally limit the plug as having an outer wall and a separate but integral central core made of a material, which is more flexible than the outer wall thus increasing the overall flexibility of the elongated cylindrical plug.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 7 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubert (US 3,572,333 A).

Hubert discloses Applicant's claimed apparatus for facilitating vascular access with the exception of the plug body, handle portion and locking mechanism being formed monolithically.

It would have been a matter of obvious design choice to have formed Hubert's elongated cylindrical plug body monolithically as no criticality has been provided in the specification, nor has it been identified as solving any particular problem in the prior art, and the Examiner contends that the prior art device whose plug body (12), handle portion (20) and locking mechanism (27, 29) are separately formed but permanently joined together, see Column 2, lines 13-15, would perform equally as well as if they were monolithically formed and as such would constitute an obvious design choice.

***Response to Arguments***

Applicant's arguments with respect to claims 1-12, 16 and 25-33 have been considered but are moot in view of the new ground(s) of rejection.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9302 for regular communications and 703.872.9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard  
August 11, 2003

*J Maynard*

*Brian L. Casler*  
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